REMARKS

Claims 1-5, 8, 10, 14-15 and 17-19 are cancelled without prejudice or disclaimer. Claims 28-31 are added. Therefore, claims 6-7, 9, 11-12, 16, and 28-31 are pending.

Claim 6 is amended to incorporate the limitations of cancelled claim 10. The remaining claims are amended to conform to the amendments made to claim 6. New claims 28 and 31 are supported by the specification at page 2, line 32. New claim 29 is supported by original claim 20; new claim 30 by pending claim 7.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Rejections Under § 112, second paragraph.

Claims 8-9 were rejected as including an improper Markush group. Claim 8 is cancelled, and amended claim 9 is no longer recites a Markush group. In light of the above amendment, this rejection may now be withdrawn.

II. Rejections Under § 102(b).

Claims 1-2 were rejected as anticipated by Lohray et al. (WO 97/417097) in view of applicant's admission. This rejection is rendered moot by cancellation of claims 1-2.

III. Rejections Under § 103(a).

A. Claims 6-16 were rejected as obvious over Lohray et al. in view of Sohda et al. (US 5,972,971). Claims 8, 10, and 14-15 are cancelled. This rejection is respectfully traversed.

The Examiner has the initial burden of establishing a *prima facie* case of obviousness. A finding of obviousness under § 103 requires a determination of the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Graham v. Deere, 383 US 1 (1966). Obviousness

cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made. In re Stencel, 828 F2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987).

Claim 6 is drawn to a pharmaceutical composition comprising 5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiadiazolidine-2,4-dione or a pharmaceutically acceptable salt thereof, and pharmaceutically acceptable excipients with low water content comprising anhydrous lactose, microcrystalline cellulose, magnesium stearate, and talc. Applicants have found that the dry formulation of claim 6 has improved stability. The pharmaceutical composition of claim 6 is not described or suggested by either cited prior art references. In light of the above amendments and remarks, it is respectfully urged that this rejection be withdrawn.

Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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6. (Amended) A pharmaceutical composition comprising
5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]
thiadiazolidine-2,4-dione or a pharmaceutically acceptable salt thereof,
and pharmaceutically acceptable excipients with low water content comprising anhydrous lactose, microcrystalline cellulose, magnesium stearate, and talc [and an antioxidant].

9. (Amended Twice) The pharmaceutical composition according to claim 6 wherein the pharmaceutically acceptable excipients are [selected among from the following:]
between 100 and 400,000 parts by weight of anhydrous lactose,
[between 50 and 500 parts by weight of pregelatinized starch,]
between 1000 and 10,000 parts by weight of microcrystalline cellulose, **and**
[between 10 and 500 parts by weight of crospovidone,
between 10 and 500 parts by weight of silicon dioxide,
between 10 and 500 parts by weight of hydrogenated vegetable oil,]
between 10 and 500 parts by weight of magnesium stearate,
[between 10 and 500 parts by weight of hydroxypropyl methylcellulose,
between 10 and 500 parts by weight of hydroxypropyl cellulose,
between 1000 and 10,000 parts by weight of Mannitol,
between 10 and 500 parts by weight of stearic acid,
between 10 and 500 parts by weight of Titanium Dioxide,]
expressed in parts by weight per 100 parts of 5-[[4-[3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiadiazolidine-2,4-dione, or of one of its pharmaceutically acceptable salts.

16. (Amended Twice) The pharmaceutical composition according to claim [1] 6, further comprising [associated with] at least one [customary additive selected from among the] sweetener[s], flavouring agent[s], colour[s] [and] or lubricant[s].